

REMARKS

The claims are 29-53, with claims 29, 30, 31, and 32 being independent. Claims 1-28 have been cancelled without prejudice or disclaimer. Support for claims 29-53 may be found in claims 1-28 and in the specification at page 6, lines 7-15, and page 8, lines 11-33. No new matter has been added.

Previously pending claims 9-10 and 18-25 were rejected under 35 U.S.C. 102(b) and claims 1-6 and 11-17 were rejected under 35 U.S.C. 103(a). Applicants respectfully traverse these rejections. Cancellation of claims 1-28 renders these rejections moot, however, Applicants will address these rejections to the extent that they apply to the newly presented claims.

Section 102 Rejection

Previously pending method of treatment claims were rejected as allegedly anticipated by Boehm (U.S. Patent 5,004,758). The Examiner contends that the method of inhibiting the growth of tumor cells using a hydrate of topotecan monohydrochloride anticipates the instant claims.

Applicants respectfully submit that Boehm fails to anticipate the present invention because Boehm fails to describe the specific crystalline topotecan monohydrochloride pentahydrate salt of the subject invention or any uses of this specific crystalline salt. Applicants note that Boehm fails to disclose the crystalline form of topotecan monohydrochloride that provides the IR and/or XRPD data defined in the pending claims, any uses thereof, or any method to prepare the presently claimed crystalline form.

The declaration submitted herewith provides the XRPD pattern for the topotecan monohydrochloride salt prepared in accordance with Example 18 of Boehm and indicates that the solid form of the topotecan monohydrochloride salt of Boehm is different from the crystalline form of the topotecan monohydrochloride pentahydrate salt of the subject application.

Accordingly, Applicants respectfully submit that because the crystalline topotecan monohydrochloride pentahydrate salt of this invention is a novel crystalline salt, any use of this novel crystalline salt is likewise novel.

Section 103 Rejection

Previously pending compound and process claims were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Boehm in view of Pothukuchi (WO 03/027118). The Examiner contends that it would have been obvious to prepare the instant polymorphic pentahydrate form of topotecan monohydrochloride.

Applicants respectfully submit that Boehm fails to support a *prima facie* case of obviousness. Applicants note that that Boehm fails to disclose or suggest the crystalline form of topotecan monohydrochloride that provides the IR and/or XRPD data defined in the pending claims. Boehm fails to describe or suggest a method to prepare the presently claimed crystalline form and nothing in Boehm provides the requisite motivation to alter the teaching therein in ways necessary to arrive at the topotecan hydrochloride crystal form of the present invention. Moreover, Boehm fails to provide the basis of any expectation that the crystalline form of topotecan monohydrochloride pentahydrate that is characterized by the IR and/or XRPD data defined in the pending claims could or would exist.

As discussed above, the declaration submitted herewith indicates that the solid form of the topotecan hydrochloride of Boehm is different from the crystalline form of the topotecan hydrochloride of the subject application.

The issue of patentability of novel crystalline forms has been specifically addressed by the CCPA and the Federal Circuit Court of Appeals, wherein the courts have held that new crystalline forms of known compounds are patentable and are not obvious over other forms of the known compound. (*In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966), *In re Irani* 427 F.2d 806, 166 USPQ 24 (CCPA 1970), *In re Grose*, 592 F.2d 116, 201 USPQ 57 (CCPA 1979) and *Bristol-Myers Co. v. U.S. International Trade Commission*, 15 USPQ 2d 1258 (Fed. Cir. 1989, unpublished)).

Bristol-Myers Co. v. U.S. International Trade Commission, 15 USPQ 2d 1258,1262 (Fed. Cir. 1989, unpublished):

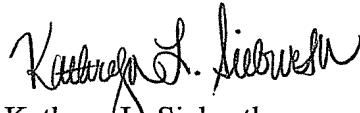
The question before the Commission was not whether the Bouzard crystal form could have been duplicated with experimentation or with even minor chemical process changes; the question was whether this new crystal form, as a composition of matter, would have been obvious from the teachings of the prior art. ...

There must be an affirmative suggestion or teaching in the prior art whereby it would have been obvious to make the new monohydrate; not simply the absence of obstacle. No such suggestion or teaching has been shown.

Appln. No.: 10/578,660
Group Art Unit No.: 1625

If the Examiner has any remaining objections or concerns, the Examiner is respectfully requested to contact Applicants' undersigned attorney using the contact information provided below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kathryn L. Sieburth". The signature is fluid and cursive, with the first name "Kathryn" and last name "Sieburth" clearly distinguishable.

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